November 10, 2021

Chip Ideas Electronics S.L.
Bernardo Plaza
Regulatory Affairs Manager
C/ Alfareria 3 B
Burjasot, Valencia 46100
Spain

Re: K212013
Trade/Device Name: eKuore Pro 4T
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: October 1, 2021
Received: October 13, 2021

Dear Bernardo Plaza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212013

Device Name

eKuore Pro 4T

Indications for Use *(Describe)*

The eKuore Pro 4T is intended to be used as a part of a physical assessment of a patient by healthcare professionals for diagnostic decision support in clinical settings. eKuore Pro 4T is intended for use on pediatric and adult patients. It can electronically filter and transfer sounds to compatible software.

It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary or abdominal organ systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

ekuore

Section 5 – 510(k) Summary

SUBMITTER

Submitter name: Chip Ideas Electronics, S.L.
Submitter address: C/ Alfarería 3 B.
46100 Burjasot, Valencia
SPAIN

Registration Number: 3017140534
Owner Operator Number: 10075275

Contact person: Bernardo Plaza Trillo
Phone: +34 640742454
e-mail: bernardo.plaza@ekuore.com

Date Prepared: 2021-10-14

DEVICE

Device Trade Name: eKuore Pro 4T
Common Name: ELECTRONIC STETHOSCOPE
Regulation Name: ELECTRONIC STETHOSCOPE
Regulatory Class: Class II
Product Code: DQD
Regulation Number: 870.1875

PREDICATE DEVICE

Predicate Device (S): eKuore Pro Series (K203007)

Section 5 – 510(k) Summary

5.1 DEVICE DESCRIPTION

eKuore Pro 4T is formed by eKuore Pro 4T device and eKuore Pro 4T Engine.

- **eKuore Pro 4T** allows use as standalone stethoscope and wireless audio transmission without smartphone to third party applications that uses eKuore Pro 4T Engine.
- **eKuore Pro 4T Engine** is a Java library that allows third party companies, communicate with eKuore Pro 4T device.

The main purpose of eKuore Pro 4T device is the detection and amplification of heart, lung, arteries, veins and internal sounds using selective frequency organ ranges.

The design of eKuore Pro 4T lets the user change the chestpiece attached between different sizes depend on the patient to be auscultated.

eKuore Pro 4T Engine Java is a Java library (.jar file) that provides management functionalities for an eKuore Pro 4T device. It provides these functionalities:

- **Stream auscultation audio** from an eKuore Pro 4T device in real-time, through a WLAN.
- Get and set additional information about the connected device:
    - The **battery level** of the device
    - The **firmware version** of the device
    - The **serial number** of the device
    - The **volume level** of the device
    - The **filter** currently being used in the auscultation
    - The **hardware version** of the device
- **Configure the connection** (IP, SSID, password, and ports) of the eKuore Pro 4T device with a router in a WLAN, allowing the device to autonomously reconnect to it when it is turned on again and stream audio.

Section 5 – 510(k) Summary

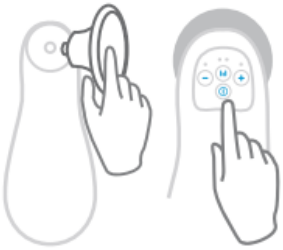
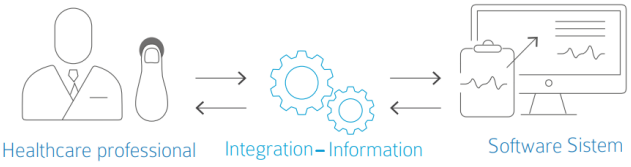
Equipment description	
	eKuore Pro 4T main piece with the chestpiece attached.
	To use the eKure Pro 4T devices the chestpice must be attached and turn it on, as is shown in the pictogram. There are three models of chestpiece depend on the patient to be auscultated. S, M or L from neonatal to adults patients.
	eKuore Pro 4T device is connected via Wi-Fi to software built using eKuore Pro 4T engine.
	eKuore Pro 4T product packaging.

Table 5.1 Equipment Description

The following table shows the difference and similarities of each eKuore Pro Series model:

Characterictic	EP0002	EP0099	EP0098
Form	Same for the three models		
Design	Same for the three models		
Material	Same for the three models		
Function	For healthcare	For healthcare	For healthcare

Section 5 – 510(k) Summary

	professionals	professionals that needs increased volume	professionals
Connectivity	Create an WLAN access point	Create an WLAN access point	It connects to an WLAN access point Configurable with eKuore Pro 4T Engine Java library
Volume control / gain	5 steps, 2 dB of difference between levels	5 steps, 2 dB of difference between levels with an offset of +6db	5 steps, 2 dB of difference between levels
Energy Supply	Same for the three models		
Software	Compatible with eKuore Pro APP.	Compatible with eKuore Pro APP.	No compatible with eKuore Pro APP. Configurable with eKuore Pro Engine Java library
Firmware	eKuore Pro FW v1.10.07	eKuore Pro FW v1.10.07	eKP4T FW v1.0.4
DSP configuration	v00.00.08	v00.00.58	v00.00.08
Hardware	Same for the three models		

Table 5.*2* - eKuore Pro models comparison table

The following table shows the technical characteristics of eKuore Pro 4T

Weight without chestpiece	85 gr
Dimensions without chestpiece	13cm x 5cm x 3cm (W x D x H)
Weight with chestpiece	150 gr
Dimensions with chestpiece	13cm x 5cm x 5cm (W x D x H)
Working temperature and humidity	0 to +40 °C and +15 to +93%
Transportation and storage temperature and humidity	-20 to +45ºC and +15 to +93%
IP Rate	IP21
Transmission frequency range	Beetween 2.412 GHz and 2.484 GHz
Modulation type	DSSS
Wireless quality of service	Device needs to be connected to wlan with at least 705kbs
Wireless security	WLAN WPA2 encrypted networks preferred.
Input voltage during the load	5V DC, 500 mA
Power	2,5 W

Section 5 – 510(k) Summary

Battery	Rechargeable. 1400 mAh lithium polymer. Do not replace by user
USB Port	Do not connect while the device iss being used with the patient
Wireless functions	Audio transmission
Wireless standard protocol	IEEE 802.11bg
Effective radiated power	15dBm (32mW)

Table 5.*3* - eKuore Pro 4T technical characteristics

5.2 INDICATIONS FOR USE

The eKuore Pro 4T is intended to be used as a part of a physical assessment of a patient by healthcare professionals for diagnostic decision support in clinical settings. eKuore Pro 4T is intended for use on pediatric and adult patients. It can electronically filter and transfer sounds to compatible software.

It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary or abdominal organ systems.

5.3 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The electronic stethoscopes are mainly used on auscultation in the detection of cardiac, respiratory sounds and check other internal organs. These types of devices are used to digitize the data of the auscultation into a mobile device.

In the establishment of substantial equivalence, eKuore Pro 4T compared to the predicate device K203007, eKuore Pro Series:

ekuore

eKuore Pro 4T
510(k) Premarket Notification

Section 5 – 510(k) Summary

Elements of comparison	New Device	Predicate device		Comparison
	eKuore Pro 4T	eKuore Pro	eKuore Pro Amplified	
Regulatory Class	Class II	Class II	Class II	Identical to predicate device
Classification name	Electronic Stethoscope	Electronic Stethoscope	Electronic Stethoscope	Identical to predicate device
Regulation Number	21 CFR 870.1875	21 CFR 870.1875	21 CFR 870.1875	Identical to predicate device
Product code	DQD	DQD	DQD	Identical to predicate device
Manufacturer	Chip Ideas Electronics, SL.	Chip Ideas Electronics, SL.	Chip Ideas Electronics, SL.	Identical to predicate device
FDA Clearance	K212013 Pending	K203007	K203007	-
USE				
Indications for use	The eKuore Pro Series is intended to be used as a part of a physical assessment of a patient by healthcare professionals for diagnostic decision support in clinical settings. eKuore Pro Series is intended for use on pediatric and adult patients. It can electronically filter and transfer sounds to compatible software. It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary or abdominal organ systems.	The eKuore Pro Series is intended to be used as a part of a physical assessment of a patient by healthcare professionals for diagnostic decision support in clinical settings. eKuore Pro Series is intended for use on pediatric and adult patients. It can electronically filter and transfer sounds to compatible software. It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary or abdominal organ systems.	The eKuore Pro Series is intended to be used as a part of a physical assessment of a patient by healthcare professionals for diagnostic decision support in clinical settings. eKuore Pro Series is intended for use on pediatric and adult patients. It can electronically filter and transfer sounds to compatible software. It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary or abdominal organ systems.	Identical to predicate device
CHARACTERISTICS				
Principles of operation	The device picks up sounds from a patient's body. This sound is filtered, amplified and sent it to the user through earbuds, also it can be sent via WiFi to eKuore Pro 4T	The device picks up sounds from a patient's body. This sound is filtered, amplified and sent it to the user through earbuds, also it can be sent via WiFi to compatible	The device picks up sounds from a patient's body. This sound is filtered, amplified + 6dB offset and sent it to the user through earbuds, also it can be sent via WiFi to	Similar to predicate device

ekuore

Section 5 – 510(k) Summary

Elements of comparison	New Device	Predicate device		Comparison
	eKuore Pro 4T	eKuore Pro	eKuore Pro Amplified	
	Engine Java.	smartphones and tablets.	compatible smartphones and tablets.	
Clinical conditions	Human body sounds related	Human body sounds related	Human body sounds related	Identical to predicate device
Use	Electronic stethoscope	Electronic stethoscope	Electronic stethoscope	Identical to predicate device
Prescription/O.T.C.	Prescription use	Prescription use	Prescription use	Identical to predicate device
Intended for Direct Connection to Patient	YES	YES	YES	Identical to predicate device
Use environment	Clinical settings	Clinical settings	Clinical settings	Identical to predicate device
Type of users	Health-care personnel	Health-care personnel	Health-care personnel with hearing difficulties	Identical to predicate device
Target population	Pediatric and adult patients	Pediatric and adult patients	Pediatric and adult patients	Identical to predicate device
Cleaning & Maintenance	When the power supply is off, the entire plastic surface can be cleaned sliding an alcohol pad. Excess fluid during cleaning can cause leakage of moisture on internal components. Clean the stethoscope from patient to patient	When the power supply is off, the entire plastic surface can be cleaned sliding an alcohol pad. Excess fluid during cleaning can cause leakage of moisture on internal components. Clean the stethoscope from patient to patient.	When the power supply is off, the entire plastic surface can be cleaned sliding an alcohol pad. Excess fluid during cleaning can cause leakage of moisture on internal components. Clean the stethoscope from patient to patient	Identical to predicate device
TECHNICAL EQUIVALENCE				
Sound track transfer function	Yes	Yes	Yes	Identical to predicate device
Signal transmission for visualization	Wireless transmission to eKuore Pro 4T Engine Java	Wireless transmission to compatible smartphones/ tablet via WiFi	Wireless transmission to compatible smartphones/ tablet via WiFi	Similar to predicate device.
Energy Source	Lithium-Ion Battery	Lithium-Ion Battery	Lithium-Ion Battery	Identical to predicate device
System required	Platform compatible with Java VM	Android device and Apple, Inc	Android device and Apple, Inc	Different to predicate device
Hardware and software platforms	Desktop or Mobile devices	Mobile devices or tables	Mobile devices or tables	Different to predicate device
Connections	Micro USB connector only to charge the internal battery of the device	Micro USB connector only to charge the internal battery of the device	Micro USB connector only to charge the internal battery of the device	Identical to predicate device

Section 5 – 510(k) Summary

Elements of comparison	New Device	Predicate device		Comparison
	eKuore Pro 4T	eKuore Pro	eKuore Pro Amplified	
Filter frequency range	• Heart (50-150 Hz) • Lung (50-500 Hz) • Extended (40-600 Hz)	• Heart (50-150 Hz) • Lung (50-500 Hz) • Extended (40-600 Hz)	• Heart (50-150 Hz) • Lung (50-500 Hz) • Extended (40-600 Hz)	Identical to predicate device
Wireless data transmission	Audio and configuration	Audio	Audio	Different to predicate device
Signal Input Method	Sound waves collected via a Transducer. Microelectro-mechanical microphone	Sound waves collected via a Transducer. Microelectro-mechanical microphone	Sound waves collected via a Transducer. Microelectro-mechanical microphone	Identical to predicate device
Audio Output Method	Earbuds connected with the device through the 3.5mm Jack directly to the eKuore device or from the device running eKuore Pro 4T engine audio output	Earbuds connected with the device through the 3.5mm Jack directly to the eKuore device or from the smartphone/tablet audio outputs	Earbuds connected with the device through the 3.5mm Jack directly to the eKuore device or from the smartphone/tablet audio outputs	Similar to predicate device
Signal Storage	Depend on platform running eKuore Pro 4T engine.	Depend on Smartphone/tablet internal memory, eKuore Pro App lets the user record 30, 60, 90 or 120 seconds. eKuore Pro Series devices does not stored data.	Depend on Smartphone/tablet internal memory, eKuore Pro App lets the user record 30, 60, 90 or 120 seconds. eKuore Pro Series devices does not stored data.	Different to predicate device
Performance requirements	Temp range: 0ºC to +40ºC Humidity range: 15% to 93%	Temp range: 0ºC to +40ºC Humidity range: 15% to 93%	Temp range: 0ºC to +40ºC Humidity range: 15% to 93%	Identical to predicate device
BIOLOGICAL EQUIVALENCE				
Body material	ABS (Acrylonitrile Butadiene Styrene)	ABS (Acrylonitrile Butadiene Styrene)	ABS (Acrylonitrile Butadiene Styrene)	Identical to predicate device
Diaphragm material	Membrane: Epoxy and Fiberglass Membrane's ring: PVC	Membrane: Epoxy and Fiberglass Membrane's ring: PVC	Membrane: Epoxy and Fiberglass Membrane's ring: PVC	Identical to predicate device
Contact with human tissues or body fluids	The chestpiece is in contact with patients' skin.	The chestpiece is in contact with patients' skin.	The chestpiece is in contact with patients' skin.	Identical to predicate device
Sterility	Not intended to be sterilized	Not intended to be sterilized	Not intended to be sterilized	Identical to predicate device

Table 5.4. Substantial Equivalence Comparison – eKuore Pro Series and Predicate Device K203007

Section 5 – 510(k) Summary

Information provided in these 510(k) submissions shows that eKuore Pro 4T is substantially equivalent to the predicate device eKuore Pro Series cleared under K203007 in terms of intended use, indications for use, compatibility, and technological characteristics. There are no new questions of safety or effectiveness.

Summary discussion of non-clinical data:

The proposed device has been designed, developed, tested, verified, and validated according to documented procedures and specific protocols in line with the following FDA guidance documents:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

General requirements for basic safety standard requirements for medical electrical equipment test have been successfully complete following standard of AAMI ANSI ES 60601-1:2005 and A1:2012 and IEC 60601-1-2 Edition 4: 2014-02 as being equivalent to the predicate device.
Integration verification and validation testing have been successfully complete following standard IEC 62304:2015.
Usability testing requirements have been evaluated and successfully met as per standards AAMI ANSI IEC 62366:2007.
Design and development included identification, evaluation, and control of potential hazards as per standard ISO 14971:2007.

Summary discussion of clinical data:
Non-clinical test data are submitted to support this premarket notification and to establish the decision concerning adequate safety and performance of the predicate device.

5.4 CONCLUSIONS

Based on the information provided in this premarket notification, Chip Ideas Electronics S.L., concludes that eKuore Pro Series is substantially equivalent to the listed legally marketed predicate device.